AUG 23 2000

K000859

Charles A. Smith
811 Starlite Dr.
Louisville, KY 40207

Non-Confidential Summary of Safety and Effectiveness

March 2000

Charles A. Smith
811 Starlite Dr.
Louisville, KY 40207

Tel - 502-969-9652 Fax - 502-969-9777

Official Contact:	Charles A. Smith
Proprietary or Trade Name:	OBA-1 - Office Based Anesthesia machine
Common/Usual Name:	Anesthesia gas machine
Classification Name:	Gas machine, anesthesia
Predicate Devices:	Medical Industrial Equipment - Hawk Anesthesia Induction Head - K981845
	Smith ThermH_2Osorb - exempt - K954280

Device Description:

The OBA-1 is an anesthesia induction unit which includes these features:

- Can be connected to a central pipeline or cylinder oxygen/air source
- Oxygen flowmeter 0 - 10 L/min
- Air flowmeter 0 - 10 L/min
- Oxygen and air pipeline pressure gauges 0 - 100 psi
- Oxygen Supply Failure Alarm
- Temperature compensated vaporizer
- Oxygen Flush valve
- Back Pressure Check valve
- Indexed Fresh Gas Common outlet with safety lock
- Patient manifold with directional valves - inspiratory and expiratory
- Adjustable APL valve with waste gas outlet connection which can be connected to an active scavenging system

- Oxygen sensor port
- Circuit Pressure monitor and gauge connection ports
- ThermH_2Osorb – sodalime CO2 absorber
- Breathing bag connection - 22 mm and breathing bag elbow

1. Intended use - The OBA-1 is intended to provide continuous gas inhalation for patient requiring anesthesia under the direct care and supervision of a trained and qualified practitioner. It provides for oxygen delivery with an anesthetic agent, via the specific vaporizer, of the practitioner's choice. It is to be used with an oxygen monitor and other suitable monitors.

2. Environment of Use - Physician office, day surgery center, dental office

3. Patient Population - Patients requiring anesthesia, in an office based setting

Comparison to Other Legally Marketed Predicate Devices

The following comparison table details the primary attributes of the intended device and legally marketed predicate devices. The most significant attributes have been listed.

A glossary of the predicate devices -

Company	Model	510(k) status
1. MIE (Medical Industrial Equipment)	Hawk Anesthesia Induction Head	K981845
2. Penlon	Sigma Elite Vaporizer	K942545
3. Clippard	Oxygen Flush valve	exempt
	One way check valve	exempt
4. Anesthesia Associates	Airway pressure gauge	preamendment
	APL valve	preamendment
	Oxygen sensor port	preamendment

5. Smith	$ThermH_2Osorb$	exempt - K954280
6. Porter Instruments	Flowmeters	exempt

Attribute	Proposed device OBA-1	Predicate Devices are listed under each attribute
Use		
Intended to provide anesthesia delivery in office or outpatient setting	Yes	1
Design		
Attaches to a central pipeline or cylinder oxygen/air source	Yes	1
Two gas flowmeters; 1 (oxygen) 1 (air)	Yes	1
Utilizes standard flowmeters	Yes	1, 6
Utilizes a disposable CO_2 absorber canister	Yes	5
Has directional valves (inspiratory/ expiratory)	Yes	1
Incorporates standard 510(k) cleared vaporizers	Yes	1, 2
Has an APL valve with gas scavenging	Yes	1, 4
Manual ventilation via a breathing bag	Yes	1
Has oxygen monitoring port	Yes	1
Has patient pressure monitoring port	Yes	1

Attribute	Proposed device OBA-1	Predicate Devices are listed under each attribute
Design (continued)		
Connects to standard anesthesia breathing circuits	Yes	1, 5
Has oxygen flush valve	Yes	1, 3
Materials		
Materials are standard for use in anesthesia gas machines	Yes	1, 2, 3, 4, 5, 6
Packaging		
Provided clean, non-sterile	Yes	1, 5
Can be cleaned and disinfected	Yes	1, 4
Performance Standards / Specifications		
None applicable under Section 514	Yes	1, 2, 3, 4, 5, 6

Differences Between Other Legally Marketed Predicate Devices

There are no functional differences between the proposed device and the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 2000

Mr. Charles A. Smith
811 Starlite Drive
Louisville, NY 40207

Re: K000859
Office Based Anesthesia Unit, Model OBA - 1™
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: July 14, 2000
Received: July 17, 2000

Dear Mr. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Pursuant to the Notice of February 6, 1996 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number: **K000859**

Device Name: Office Based Anesthesia machine - **OBA-1™**

Intended Use : The Office Based Anesthesia Unit - OBA-1™ is intended for administration of general inhalation anesthesia using mixtures of oxygen, air and volatile anesthetics, and for providing breathing gas and for either spontaneous ventilation or controlled ventilation of patient lungs.

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

Division of Cardiovascular & Respiratory Devices

510(k) Number K000859

Prescription Use ✓ **or** **Over-the-counter use** __

(Per CFR 801.109)